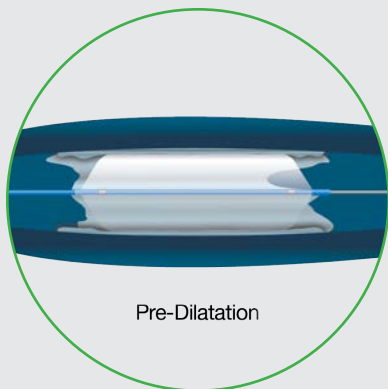


# LUTONIX<sup>®</sup> 035 DCB Catheter Procedure

**NOTE:** This procedure overview is not intended as a replacement for the full instructions for use. Please see the IFU for complete preparation and deployment instructions, as well as additional contraindications, warnings and precautions.



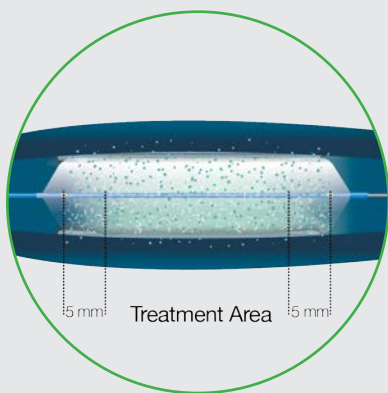
## Step 1: Pre-Dilatation

Adequately pre-dilate to achieve  $\leq 30\%$  residual stenosis prior to DCB use. Pre-dilatation with ultra-high pressure (fiber) is recommended

**Advance to the target site in the shortest possible time. (i.e.  $\leq 30$  seconds)**

## Step 2: DCB Transit

Size the DCB so its diameter is  $\geq 1:1$  to the pre-dilatation balloon. To ensure therapeutic drug delivery, the LUTONIX<sup>®</sup> 035 DCB should be advanced to the target site in the shortest possible time (i.e.  $\sim 30$  seconds) and immediately inflated to appropriate pressure to ensure full wall apposition. If the deployment of LUTONIX<sup>®</sup> 035 DCB exceeds 3 min., the catheter requires replacement with a new unit. Always advance the catheter under negative pressure. Do not immerse the balloon in a saline bath.



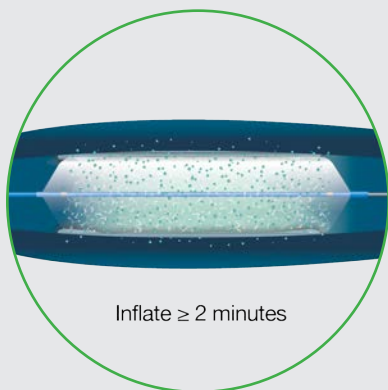
## Step 3: DCB Placement

LUTONIX<sup>®</sup> 035 DCB should extend approximately 5 mm proximally and distally beyond the pre-dilatation injury segment. The GEOALIGN<sup>®</sup> Marking System is available on LUTONIX<sup>®</sup> 035 DCB.

**LUTONIX<sup>®</sup> 035**  
Drug Coated Balloon PTA Catheter

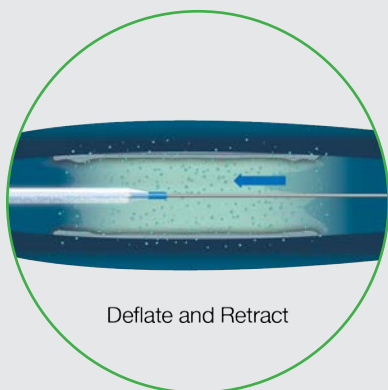
**BARD**

# LUTONIX<sup>®</sup> 035 DCB Catheter Procedure



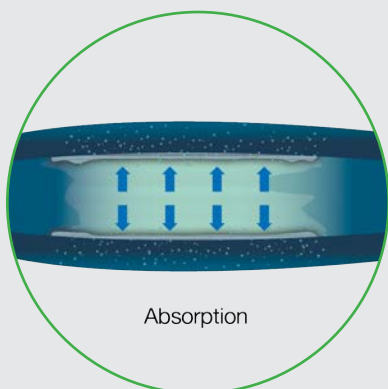
## Step 4: Balloon Preparation

Maintain balloon inflation for a minimum of 2 minutes (120 seconds). The balloon may remain inflated as long as is required by the standard of care to achieve a good angioplasty outcome. Do not exceed the recommended Rated Burst Pressure (RBP) during inflation. The balloon transfers the therapeutic drug dose during this initial inflation.



## Step 5: Balloon Removal

Apply negative pressure to fully deflate the LUTONIX<sup>®</sup> 035 DCB. Prior to removal, confirm that the balloon is fully deflated under fluoroscopy. Withdraw the LUTONIX<sup>®</sup> 035 DCB from the body under negative pressure. Maintain the guidewire across the stenosis.



## Step 6: Drug Effect

Paclitaxel diffuses into the arterial wall from the endoluminal surface after drug delivery and is designed to decrease the incidence of restenosis and improve patency.

**LUTONIX<sup>®</sup> 035**  
Drug Coated Balloon PTA Catheter

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Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions. Rx only.

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